



**COMPANY  
PROFILE**



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OUR  
MISSION

## Italian Passion. German Quality.

The company BONTEMPI produces and sells high quality German surgical instruments (AISI 421 - 440C steels) and has been operating on the market since 1974.

Currently we are present in the main foreign markets, with an absolutely avant-garde production and a strict Quality Control certified according to the EEC and ISO 9001 and 13485 standards.

Our production of instruments includes all the lines of Surgery (Dentistry, Implantology, Parodontology, Orthodontics, Maxillofacial, Aesthetic Surgery, Plastic Surgery, Veterinary and all sectors of General Surgery and Hospital).

The superior quality of our instruments lies in the special martensitic steel alloys of which they are composed, which, associated with an excellent quality / price ratio, finds continuous approval and approval in all markets.

### DENTISTRY

Dental Surgery  
Implantology  
Orthodontics  
Endodontics  
Periodontology  
Maxillofacial surgery

### PLASTIC SURGERY

Plastic and Reconstructive  
Breast Surgery  
Rhinoplasty  
Blephar and Otoplasty  
Liposuction and Lipofillin  
Facelift

### VETERINARY SURGERY

Veterinary Surgery  
Dental Surgery  
Ophthalmology  
Otolaryngology  
Traumatology  
Big animals

### GENERAL SURGERY

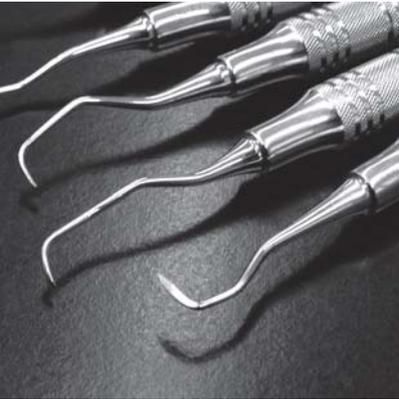
General surgery  
Otolaryngology  
Microsurgery  
Ophthalmology | Traumatology  
Arthroscopy Gynecology  
Podology and Aesthetics

Our complete instrumentation lines, comprising over 11,000 items, are designed and manufactured in Germany with special German steels and are guaranteed for five years from construction defects.

The design and finishing of our surgical instruments are specially designed to help and improve the work of the surgeon, in the constant pursuit of excellence. All the BONTEMPI tools that, according to our specific experience are more common use, are available for immediate delivery.

BONTEMPI has a specific service for its customers offering the repair and reconditioning of all its instruments, as well as the replacement of tungsten inserts (Scissors, Port'aghi and Tweezers).

We are also able to customize, with LASER writing, or by means of the Electrolysis procedure, every type of instrument, affixing the name of the Study, of the Department, and / or Name of the Doctor.



## Dichiarazione di Conformità

within the meaning of Directive 93/42/CEE and subsequent amendments and additions as per Directive 2007/47/CE transposed by Legislative Decree no. 37 of 25.10.2010 concerning medical devices

Hereby, the

### **Bmed S.r.l.**

**Via Mincio 166 - San Giovanni Marignano (RN) Italy**

declare under our sole responsibility that the products sold under the name " Bontempi " and marked with the marking **CE** comply with the provisions of the relevant Directive 93/42/CEE and subsequent amendments and additions Directive 2007/47/CE as transposed by Legislative Decree no. 37 of 25.01.2010 concerning medical devices.

Reference categories of products INSTRUMENTS:

- **Instruments of General Surgery**
- **Instruments of Plastic Surgery**
- **Dental instruments**
- **Instruments of Veterinary Surgery**

These products have been classified into class I in accordance with Annex IX.

Bmed Srl also makes available to the competent authorities , at their location , a copy of the documentation required by that Directive for consultation.

This commitment is valid for five years , after switching off the production of the product concerned.

San Giovanni in Marignano,  
**Bmed Srl**

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**Gianmaria Vagnini**  
(Legal Representative)

DECLARATION  
OF CONFORMITY

## Zertifizierung der Herkunft für chirurgische Instrumente

### Certification of origin for surgical instruments

### Certificazione di origine per strumentario chirurgico

Wir erklären hiermit, das folgende:

*We hereby declare the following:*

*Con la presente siamo a dichiarare quanto segue:*

- **Die chirurgischen Instrumente Bontempi ist mit speziellen Stählen in deutscher hergestellt DEUTSCHLAND - Tuttlingen und wird für fünf Jahre gegen Fabrikationsfehler garantiert**  
*The Bontempi Surgical Instrumentation is manufactured with special german steels in GERMANY - Tuttlingen and is guaranteed for five years against manufacturing defects*  
*Lo strumentario chirurgico BONTEMPI viene fabbricato con acciai speciali tedeschi in GERMANIA - Tuttlingen e viene garantito per cinque anni da difetti di costruzione*
- **Chirurgische Instrumente Bontempi wird durch das Verfahren des Schmelzens Formen hergestellt**  
*The Bontempi Surgical Instruments is manufactured by the method of smelting molds*  
*Lo strumentario chirurgico BONTEMPI viene fabbricato con il metodo di fusione dell'acciaio su stampi*
- **Die verwendeten Stähle sind Stähle definiert. Series martensitischen AISI 421 - AISI 440 - AISI 440.C, vollständig Korrosion UNI X20Cr13 - X30Cr13 - X40Cr14, DIN 1.4021 - DIN 1.4043**  
*The steels used are defined steels - Martensitic series AISI 421 - AISI 440 - AISI 440.C, completely anticorrosion, UNI X20Cr13 - X30Cr13 - X40CR14, DIN 1.4021 - DIN 1.4043*  
*Gli acciai utilizzati sono definiti inossidabili - Martensitici serie AISI 421 - AISI 440 - AISI 440.C, completamente anticorrosivi, norme UNI X20CR13 - X30CR13 - X40CR14, DIN 1.4021 - DIN 1.4043*
- **Alle Instrumente sind in Übereinstimmung mit dem Antrag der Standard unseres Landes gebaut und nach EWG Europäischen Union.**  
*All the instruments are constructed in accordance with the request of the standard of our country and according to EEC European Union.*  
*Tutto lo strumentario è costruito conformemente alla richiesta dello standard del nostro paese e secondo la normativa CEE Europea.*

**ORIGIN OF THE  
MATERIAL**

## Zertifizierung der Herkunft des Materials

### Certification of origin of the material

### Certificazione di origine del materiale

**BONTEMPI**

**Chirurgische Instrumente**

Bmed Srl

Via Mincio, 166

47842 San Giovanni in Marignano (RN) Italy

**Erklären in alleiniger Verantwortung, dass die chirurgischen Instrumente von uns, auf die dieses Zertifikats bezieht sich natürlich im Lieferumfang martensitische Stähle AISI 4000-Serie, die auch als OP-Stahl, dessen chemische Zusammensetzung ist wie folgt aufgebaut ist bekannt:**

*Declare under our sole responsibility that the surgical instruments supplied by us to which this course certificate relates is built with martensitic steels AISI 4000 series, also known as Surgical Steel, whose chemical composition is as follows:*

*Dichiara sotto la propria esclusiva responsabilità che lo strumentario chirurgico da noi fornito al quale questo Certificato si riferisce è costruito con acciai martensitici serie AISI 4000, detti anche Acciai Chirurgici, la cui composizione chimica è la seguente:*

|        |         | <b>C</b> | <b>Cr</b> | <b>Si</b> | <b>Mn</b> | <b>P</b> | <b>Ni</b> | <b>S</b> |
|--------|---------|----------|-----------|-----------|-----------|----------|-----------|----------|
| 1.4021 | X20Cr13 | 0,19%    | 13,20%    | 0,46%     | 0,44%     | 0,024%   | -         | 0,003%   |



## General report Stainless Steel and material

The Bontempi manufactures its products using materials tested, compatible with the particular intended use. We make every effort to make sure that the materials used meet the requirements specified in the specific product standards, if they exist.

Below are listed the materials we use in production. For each of them is a brief description of the features. In the "Fact Sheet" for each item is quoted on the type of steel would be more appropriate on the basis of business and the characteristics required.

The contract "Own Brand Labeler" entered into with the supplier guarantees that the supplier retains the Certificate of Material and that the materials used for the production of the devices provided to Bontempi are biologically compatible.

### Stainless Steel

The Stainless steels are alloys based on iron, chromium and carbon and also other elements such as nickel, molybdenum, silicon, titanium, which make them particularly resistant to corrosion. According to the regulations defining those steels in which the percentage of chromium is at least equal to 11%. We can distinguish stainless steels into three families based on the metallurgical structure that distinguishes them:

- **MARTENSITIC:** curable with a heat treatment;
- **FERRITIC:** a stable structure independently of the temperature;
- **AUSTENITIC:** a stable austenitic structure regardless of the temperature.

Martensitic steels are those containing a quantity of C. between 0.1 and 0.5% with peaks of 1% and the Cr content. Approximately between 11 and 18%.

Ferritic stainless steels are those with a Cr content. Between 16 and 30% and very low levels of C to below 0.1%. Austenitic steels are those that in addition to Cr. In reason of 15-26% also contain Ni equal to 6-22% and the levels of C very low with a maximum of 0.2%. One of the peculiar characteristics of stainless steels is precisely their corrosion resistance: this, however, must not be understood in an absolute sense; calibrate it must instead use the type of stainless steel in the work environment and the mechanical characteristics requests, which act directly on the conditions of assets or liabilities of stainless steel.

### AISI (American Iron and Steel Institute)

#### Austenitic stainless steel (AISI 300 series):

No Quenchable but have excellent corrosion.

They are used usually for the handles for which there are no special requirements of hardness. Special materials of this family, with good elastic properties, are also used for

MADE IN  
GERMANY



some types of probe.

The contract "Own Brand Labeler" entered into with the supplier gives us control of the supplier of the certificate of origin of the material to verify that the mechanical properties of the material are in the range of acceptability fixed in the tables of classification.

#### **Martensitic stainless steel (AISI 400 series)**

Are essentially steels with chromium (11% -18%) that may contain small amounts of other elements. A fundamental characteristic of these steels is the aptitude to better their mechanical properties by heat treatment of quenching and tempering; varying the temperature can be reconciled good mechanical properties with a good corrosion resistance. Some martensitic stainless steels have good characteristics of resistance to hot creep at temperatures up to 650 °, with a good resistance to flake chin in an oxidizing atmosphere up to 700 ° C.

The welding of these steels are some difficulties when the carbon content exceeds 0.15% -0.20%.

In all cases you get good welds with suitable thermal treatments preheating and annealing. And 'advisable, welding electrodes, use those martensitic stainless steel. Martensitic stainless steels are particularly suitable for application that require high mechanical strength, hardness, abrasion resistance together with a sufficient resistance to corrosion.

### **Main steel for the construction of surgical instruments**

#### **Stainless Steel AISI 420**

Martensitic steel with distinctive mechanical properties that make it suitable for different applications. In the hardened and relaxed with polished surfaces, has good resistance to corrosion in aggressive environments using non-chlorinated.

#### **Stainless Steel AISI 420C**

Stainless martensitic hardenable to obtain a hardness greater than 52 HRC. The maximum corrosion resistance is achieved in the hardened and relaxed after polished. There is no use for welded parts.

#### **Stainless Steel AISI 440A 440B 440C**

Martensitic stainless steel with high levels of C and Cr with equally high hardness after quenching (approx. 57 HRC). Hardened and after polishing has good resistance to corrosion in air, fresh water, fuel, food.

The carbon content of this steel is approximately:  
A (0.75%) B (0.9%) C (1.2%) .440 C is a stainless steel

excellent, usually around 56-58 Rc, very hard and with good sealing from the cut.

### **Quenching and tempering**

The materials normally used for the production of surgical instruments are hardenable chromium steels, high carbon content "AISI (American Iron and Steel Institute) 440 and AISI 420", in other words martensitic stainless steels, which contain at least 12 Chromium, the potential of which can be developed with an appropriate cycle of construction and heat treatment. Martensitic stainless steels are alloys of iron, carbon and chromium, which very often to improve and increase the rust resistance, hardness, and toughness, are added other elements such as vanadium, molybdenum, nickel, tungsten. The best distribution, union and fusion of these elements between them, allows to realize a high quality steel.

#### **Hardening**

To make the best use of the potential martensitic stainless steel, we use the heat treatment or tempering. The alloy steel other elements develops special properties according to the characteristics that you want to enhance depending on the use. Generally what turns an alloy steel in a steel cutlery is optimal for the heat treatment (quenching and tempering). Each alloy is characterized by a critical temperature at which the crystalline structure of the steel outline increasing the solubility of carbon in the ferritic matrix: this temperature must be maintained to achieve the austenitization of the steel but not so much as to promote the growth of the size of graininess.

The next step is to quench the temperature (operation temperature) with various media (water, oil, emulsions saline, ice, air, etc..) To obtain the desired level of hardness.

#### **Tempering**

After quenching, the steel is very hard but also very fragile: to obtain a good compromise between hardness (which translates into longer duration of the wire) and decrease the fragility (which translates into greater shock resistance), is always executed a second heat treatment (tempering operation), the purpose of which is to stretch the material subject to the state of internal compulsion, induced by hardening to remove residual stresses.

#### **Materials used during processing**

Are also used for producing various types of abrasive pastes vibratory finishing, etc.. The residues of these substances are in each case eliminated before the final packaging by washing - ultrasonic washing.

## Elements of the steels

### Carbon C

Present in all steels is the element that transforms iron into steel by characterizing the elasticity increasing the hardness of the tool to the tool life. Consider that the average of steel must have a > 0.5% of carbon to be defined as "high carbon".

### Chromium Cr

Element that increases wear resistance, fatigue and corrosion. A steel with at least 10-14% chromium is typically deemed "stainless" steel, although the definition would not be entirely accurate because, despite the name, all steel can oxidize if not carried out any maintenance.

### Cobalt Co

Increases strength and hardness and allows to withstand high temperatures multiplies the effects of other alloying elements.

### Manganese Mn

Important element, since the manganese helps the structure to raise the capacity and improves the hardness of steel, deoxidises degassed and the metals during thermal treatments.

### Molybdenum Mo

Prevents the fragility (disease Krupp fragility to tempering) and increasing toughness and fatigue resistance, increases the workability and corrosion resistance.

### Nickel Ni

Increases the hardness and strength. Nickel can also play the role in the corrosion resistance as well, but is definitely not valid such as chromium and should be used with a high percentage at the expense of the sealing wire.

### Phosphorus P

Decreases if the fragility in high concentrations increases the resistance, workability and therefore more resistance and greater hardness.

### Aluminium Al

Only for handles because of good workability and lightness. The material does not enter into contact with the patient. There are no problems for sterilization.

### Teflon

Material with high biological compatibility. Used for internal components of the pliers. The sterilization does not involve the decay characteristics.

### Titanium

The new titanium alloys provide high performance, are extremely resistant to oxidation, light, resistant to abrasion and non-magnetic. For the particular difficulty of processing, have a high cost.

### Titanium Nitride

Material used as a non-stick coating in some tools used for modeling pastes and composites.

### Tungsten Carbide

Used to increase the wear resistance of certain surfaces as in the case of Needle Holders, tweezers and in the blades of the scissors to increase the duration of the cut.

### Pottery

The ceramic tools, in particular the scissors, blades have harsh obtained using zirconium enriched with magnesium, silicon and calcium. The ceramic offers unique features such as an estate of the cutting edge above the average, maximum hygiene thanks to the inert material of construction that does not cause reactions with the tissues with which it comes into contact and is easy to clean.

### Paints

Polyurethane-based paints are used for the coloring of some of the handles of tools in place for identification purposes. Once dry the paint is stable and is not affected by the agents normally present within the use of the instrument. The patient is not in contact with the paint since this is not applied on the working surfaces but only on a part of the handle. Your health care professional to properly utilize latex gloves does not absorb pigment neither affects the layer of paint. Therefore, the color has no effect on the patient or the operator.

### Gold

Used for special products with special aesthetic requirements only on the handles. The element is in any case very well tolerated by the human body.

### Glass

Used for the construction of mirrors. No problem of compatibility with the tissues, nor with the sterilization.

### Rhodium

Used to coat the outside of the area of reflective mirrors. The material element is not attacked by acids and is inert.



## Instruction and method of use

Bmed each instrument is produced and controlled with the utmost care and is intended solely for personal use professionally qualified and for which it was conceived and realized.

### First use

The instrument is supplied in a "NON STERILE" and imbued with a special liquid oily in cycles, parts and pivoting in those screwed. **Therefore, before use, you must good wash the instruments using neutral detergent and / or degreasers suitable for steel, so as not to cause unpleasant complications with the instrument (red spots, induration pivoting shares etc..).**

### Cleaning

After using the instruments, rinse immediately to remove all waste, using a brush with stiff plastic bristles (NO METALS), or to prevent contact, soak the instruments in a disinfectant solution-DETERGENTE for at least 10 minutes.



Avoid cleaning in ultrasonic bath for all those tools with cutting phase (scissors, scalpels, ossivore, chisels) and carryover Tungsten carbide, as they may chip, remove or encroach on the welds of plachette.

**DO NOT EVER PUT OTHER INSTRUMENTS OF MATERIAL IN THE CYCLE OF CLEANING.**

After cleaning make sure that the instruments are perfectly dry and lubricate moving parts, hinges, joints, with specific products for surgical instruments (NO INDUSTRIAL LUBRICATING OILS OR)

### Sterilization

Sterilize the instruments only after a thorough cleaning and their lubrication. It is also important to follow the instructions of the manufacturer of equipment used for sterilization.

**STEAM STERILIZATION (AUTOCLAVE)** - does not exceed 134 ° C, the instruments with hinges at joints should never be closed (metal against metal) or near the joints or hinges, to the explosion due to heat, you could create cracks.

**STERILIZED STOVES OR DRY** viewed the high temperatures that are reached for sterilization can occur, particularly for cutting tools (scissors, forceps, chisels) reduced early the blades and a slight browning of the instrument itself.

**STERILIZING COLD:** suggest solutions to basic pH and to respect the time of immersion of the instruments in a sterilizing liquid.

### Warnings

The tools used, damaged, oxidized should not be used because they are no longer able to perform their function. Please note that some types of damage (corrosion, rust spots and the like) are transmitted to the instruments intact.

Failure to follow these basic rules may irreparably harm the instrument and will invalidate any right of replacement or warranty claim against Bmed.

INSTRUCTIONS  
AND METHOD  
OF USE



## General technical data sheet

within the meaning of EEC directive 47/2007 on medical devices

### ALLOY USED

- Austenitic stainless steel (AISI 300 series)
- Martensitic stainless steel (AISI 400/420/440/440C series)

### RULES APPLICABLE TO THE PRODUCT

EEC Directive 47/2007, according to the rule of Annex IX to the product has been classified in Class I.

### CLINICAL VALIDATION

Magazines, Publications scientific medical literature and letters of doctors give evidence of clinical validations.

### PACKAGING

The product is packed in transparent plastic bags, non-sterile. This value pack offers adequate protection and allows the product to reach the final customer in safe hygienic conditions.

### WARNINGS

Store in a dry place. Each instrument BONTEMPI is intended for qualified personnel and the use for which it was designed and implemented. The instruments worn, damaged, oxidized must not be used, since they are not in condition to perform their function. It is recalled that some types of damage (corrosion, dots of rust and the like) are transmitted to the instruments intact for contact.

### INSTRUCTIONS FOR USE

The instrument is supplied in condition NOT STERILE and should be checked, cleaned, washed and sterilized before each use and after each intervention. Remove any deposits of organic residues and other corrosive substances using specific products, in concentrations and within the time specified by the manufacturer. Periodic checks of the proper functioning of the equipment sterilization, autoclave or other systems used by you.

For steam sterilization (autoclaving) will not exceed 134 ° C. Failure to comply with these basic rules can cause irreparable damage to the instrument and will invalidate any warranty replacement or right of recourse against the Bmed Srl.

The warranty does not cover general maintenance (eg, sharpening, replacing Spring / Screw / TC plates).

Bontempi instruments are subject to EC Directive 47/2007 and should therefore be disposed of in accordance with regional regulations.

## Dentistry



**Odontoiatria**  
Cod. Catalogo: D-4-5



**Implantologia**  
Cod. Catalogo: D-4-4



**Ortodonzia**  
Cod. Catalogo: D-4-3



**Maxillo-Facciale**  
Cod. Cat.: MX-1-10



**Container**  
Cod. Catalogo: CT3-15

## Plastic Surgery



**Chirurgia Plastica**  
Cod. Catalogo: P-1-22



**Chirurgia Plastica New**  
Cod. Catalogo: P-03-05



**Cannule Liposcultura**  
Cod. Catalogo: PC-1-14

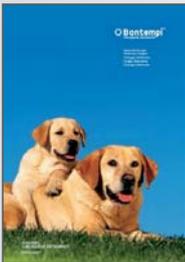


**Container**  
Cod. Catalogo: CT3-15

All Bontempi catalogs  
are available for download at:  
[www.bontempimed.com](http://www.bontempimed.com)

or, upon request,  
they can be consulted via CD

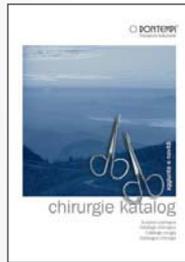
## Veterinary Surgery



**Chirurgia Veterinaria**  
Cod. Catalogo: V-1-13



**Chirurgia Generale**  
Cod. Catalogo: C-1-01



**Chirurgia Generale New**  
Cod. Catalogo: C-2-02

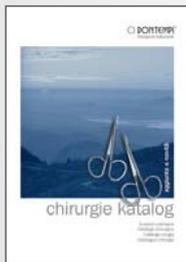


**Container**  
Cod. Catalogo: CT3-15

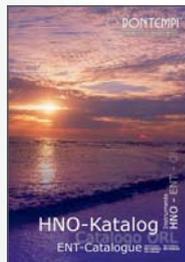
## General Surgery



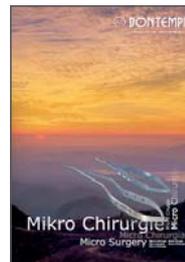
**Chirurgia Generale**  
Cod. Catalogo: C-1-01



**Chirurgia Generale New**  
Cod. Catalogo: C-2-02



**Otorinolaringoiatria**  
Cod. Catalogo: HN-1-22



**Micro-Neuro**  
Cod. Catalogo: D-4-5



**Traumatologia**  
Cod. Catalogo: D-4-5



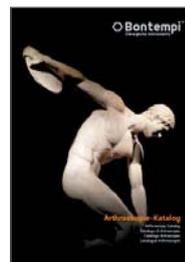
**Oftalmologia**  
Cod. Catalogo: D-4-5



**Container**  
Cod. Catalogo: D-4-5



**Ginecologia**  
Cod. Catalogo: D-4-5



**Artroscopia**  
Cod. Catalogo: D-4-5



**Podologia - Estetica**  
Cod. Catalogo: D-4-5

**BONTEMPI  
CATALOGS**

## ISO Certificats

Fields of Activity: Design, production and assistance of medical devices and instruments not active for General Surgery, Dentistry and Veterinary Surgery

For information on the validity of the certificate, visit [www.rina.org](http://www.rina.org)



ISO  
CERTIFICATES  
COMPANY  
REFERENCES

**ISO 9001:2015**  
Certificato n. 31756/15/

**EN ISO 13485:2016**  
Certificato n. DM/15/108/

## Company references

|                              |                        |  |
|------------------------------|------------------------|--|
| Commercial office            | Patrizia Cevoli        | <a href="mailto:commerciale@bmedsurgery.it">commerciale@bmedsurgery.it</a>       |
| Administration Office        | Antonella Palermo      | <a href="mailto:amministratore@bmedsurgery.it">amministratore@bmedsurgery.it</a> |
| Secretariat and Events       | Lucia Protti           | <a href="mailto:segreteria@bmedsurgery.it">segreteria@bmedsurgery.it</a>         |
| Production Manager           | Gianmaria Vagnini      | <a href="mailto:gianmaria@bmedsurgery.it">gianmaria@bmedsurgery.it</a>           |
| Commercial Manager           | Guglielmo Della Bianca | <a href="mailto:g.dellabiancia@bmedsurgery.it">g.dellabiancia@bmedsurgery.it</a> |
| Resp. Graphics and Marketing | Marco Galvani          | <a href="mailto:marco@bmedsurgery.it">marco@bmedsurgery.it</a>                   |
| Information                  |                        | <a href="mailto:info@bontempimed.com">info@bontempimed.com</a>                   |

## Contact

**BONTEMPI**  
CHIRURGISCHE INSTRUMENTE

BMED Srl - Via Mincio, 166  
47842 San Giovanni in Marignano RN  
C.F. e P.Iva 04006860409

T +39 0541 1799990  
F +39 0541 1794330  
[bontempimed.com](http://bontempimed.com) / [info@bontempimed.com](mailto:info@bontempimed.com)



FM-311 BONTEMPI 14 21314  
Germany Stainless Steel

FM-338 BONTEMPI 14 21314  
Germany Stainless Steel

FM-306 BONTEMPI 14 21314  
Germany Stainless Steel



**BMED Srl** - Via Mincio, 166  
47842 San Giovanni in Marignano RN  
C.F. e P.Iva 04006860409

T +39 0541 1799990  
F +39 0541 1794330  
bontempimed.com / info@bontempimed.com

**BONTEMPI**  
CHIRURGISCHE INSTRUMENTE