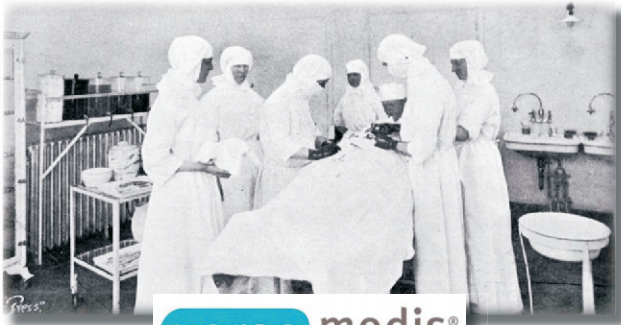


1900



versa modis®

improves life



2009



CIBG
Ministerie van Volksgezondheid,
Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Versagrip B.V.
T.a.v. de heer Dr. T.S. Oel
Julianalaan 45
2051 JL OVERVEEN

Datum: 27 april 2009
Betreft: aanmelding klasse I **Versamodis**

Geachte heer Oel,

Op 19 januari 2009 ontving ik uw aanvraag krachtens artikel 5 lid 1 van het Besluit medische hulpmiddelen van 30 maart 1995 om onder uw bedrijfsnaam "**Versagrip B.V.**" een medisch hulpmiddel klasse I op de Europese markt te brengen:

Merknaam: **Versamodis**

Het product staat geregistreerd als medisch hulpmiddel klasse I onder nummer:

2907670

U wordt verzocht dit nummer te gebruiken in alle verdere correspondentie betreffende bovenvermeld product. Aan dit nummer kunnen geen verdere rechten otleend worden; het dient alleen om de notificatie administratief te vergemakkelijken.

De registratie van medische hulpmiddelen klasse I op grond van de Classificatiecriteria bij Europese Richtlijn 93/42/EEG betreffende medische hulpmiddelen, is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voortschrijdend wetenschappelijk inzicht (zie art. 9, lid 3 van Europese Richtlijn 93/42/EEG).

Voor wat betreft de wettelijke bepalingen die een fabrikant van medische hulpmiddelen bij het in de handel brengen van zijn producten in acht dient te nemen, vestig ik volledigheidshalve uw aandacht op het Besluit medische hulpmiddelen van 30 maart 1995.

Unit Farmatec-BMC

Bezoekadres:
Wijnhaven 16
2511 GA Den Haag
T 070 340 5200
F 070 340 7426
www.farmatec.nl
info@farmatec.nl

Intichtingen bij:
A. Klasing
a.klasing@minvws.nl

T 070 340 79 48

Ons kenmerk:
Farmatec/FZ 292884

Bijlagen

Uw brief
15 januari 2009

Het CIBG is een uitvoeringsorganisatie van het Ministerie van Volksgezondheid, Welzijn en Sport

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Versagrip B.V. (Chamber of Commerce number 34238297) has been founded in 2006 by an orthopaedic surgeon in the Netherlands.

The company has developed new ergonomic handles for manual instruments which are patented. Main purpose of the handle is for tools used during surgery.

The traditional tools are literally antique, because they were developed in the late 18th century, and were never changed since then. These handles do not meet today's requirements of ergonomics. As a frequent user, the founder of the company experienced how tiring these handles are.

In collaboration with the department of industrial design of the Technical University Delft, the Netherlands, new handles were developed. The new handles are very welcomed by the OR nurses and surgeons, because they feel very comfortable.

The instruments are sold under the name Versamodis® (www.versamodis.com). Eleven types of retractors are available now. New types of instruments can be made on demand.

The new instruments are CE registered as a class 1 medical tool under number 2907670.

The instruments are of the same alloy as the traditional ones. Sterilization, packaging and storage are therefore equal.

Besides the ergonomic instruments, the company offers also the traditional instruments, including scissors, forceps etc. The company guarantees an excellent quality at a good value for money.

In cooperation with the distributor, (scientific) presentations can be given at hospitals, exhibitions, and meetings.

Please, feel free to try the difference, and share the experience.

San Oei, MD PhD
orthopaedic surgeon, CEO



versa modis®

www.versamodis.com



VOLKMANN

VOR2 Blunt - two prongs
VOR3 three prongs

Handle 20 mm
Length 21.5 cm

VOR4 Blunt - four prongs
VOR5 six prongs

Handle 25 mm
Length 21.5 cm

VOR7 Sharp - two prongs
VOR8 - three prongs

VOR9 Sharp - four prongs
VOR10 six prongs

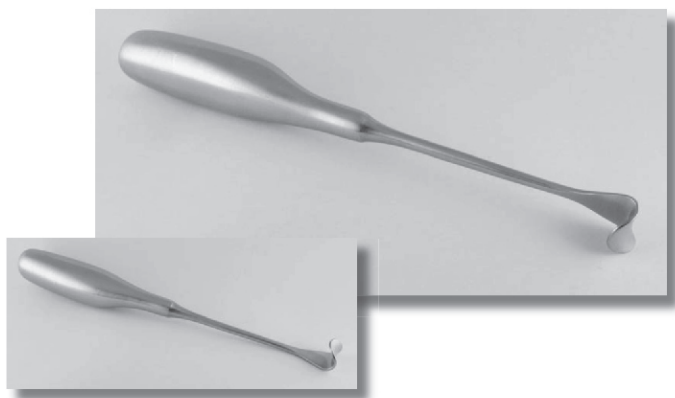


VOLKMANN

VOR1 Blunt - one prong

VOR6 Sharp - one prong

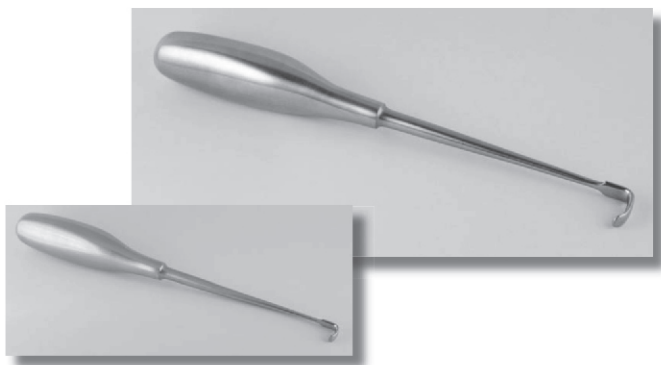
Handle 25 mm
Length 23 cm



CUSHING

CD01	Blade - 10 mm
CD02	12 mm
CD03	14 mm
CD04	16 mm
CD05	18 mm

Handle 20 mm
Length 21.5 cm



RAGNELL

RA01 Blade - 5x3 mm

RA02 - 14x6.3 mm



KOCHER

KO01 Blade - 19x12 mm

KO02 - 21x14 mm

Handle 25 mm

Length 23 cm



MIDDELDORPF

MID01 Blade - 14x17 mm

MID02 - 20x22 mm

MID03 - 26x30 mm

Handle 25 mm

Length 22 cm



LANGENBECK

LA01 Blade - 30x11 mm

LA02 - 30x14 mm

LA03 - 30x16 mm

LA04 - 40x11 mm

LA05 - 50x11 mm

Handle 25 mm

Length 22 cm



FARABEU

FAR1 Blade - 12.5 mm
- straight

FAR2 12.5 mm
curved

Handle 25 mm
Length 15 cm



BREISKY-OEI

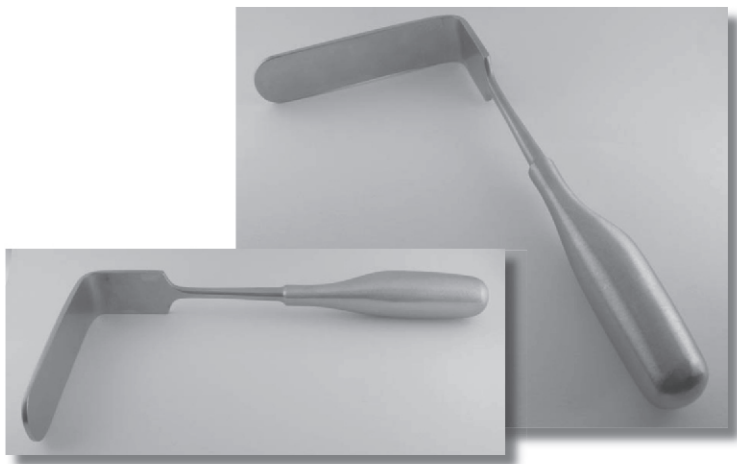
BRO1 Blade - 2 cm

BRO2 - 3 cm

BRO3 - 4 cm

Handle 25 mm

Length - 20 cm



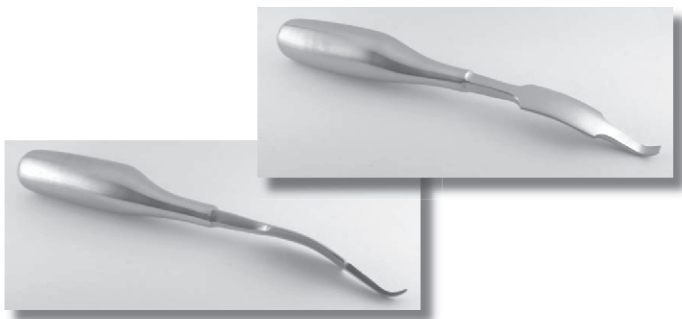
BRUNNER-SIMON

BS01 Blade - 115X22 mm

BS02 - 115x27 mm

Handle 25 mm

Length 26 cm



HOHMANN

- HOL1** Blade - 8 mm
- HOL2** - 12 mm
- HOL3** - 18 mm
- HOL4** - 43 mm

Handle 25 mm
Length 26 cm



VOLKMANN CURETTES

- VOC1 Blade - 2.8 mm
- VOC2 - 3.8 mm
- VOC3 - 4.8 mm
- VOC4 - 5.8 mm
- VOC5 - 6.8 mm
- VOC6 - 8.3 mm
- VOC7 - 10 mm
- VOC8 - 11.5 mm
- VOC9 - 12.5 mm
- VOC10 - 13.7 mm

Handle 25 mm
Length 23 cm

Skalpelli-Griffe
 Scalpel Handles
 Mangos de bisturís
 Manici per lama bisturi

passend zu den Klängen
 for blades
 para las hojas
 per lama bisturi

- Ⓐ No. 10, 11, 12, 13, 14, 15, 16, 17, 18, 19
- Ⓑ No. 20, 21, 22, 23, 24, 25



07103-00
 Fig. 3
 Ⓐ



07103-01
 Fig. 3 grad.
 Ⓐ



07103-02
 Fig. 3 L
 Ⓐ



07109-03
 Fig. 3 L
 Ⓐ

Skalpelli-Griffe
Scalpel Handles
Mangos de bisturís
Manici per lama bisturi



07104-00
Fig. 4

ⓑ



07104-02
Fig. 4 L

ⓑ



07105-02
Fig. 4 L

ⓑ

Skalpell-Griffe
 Scalpel Handles
 Mangos de bisturíes
 Manici per lama bisturi



07107-00
 Fig. 7

(A)



07107-01
 Fig. 7K

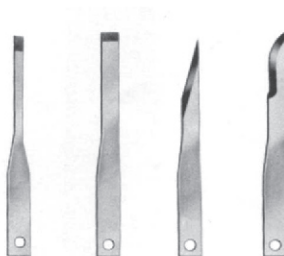
(A)



07108-00
 Fig. 8

(B)

Skalpelli-Griffe
Scalpel Handles
Mangos de bisturíes
Manici per lama bisturi



07161-00 07162-00 07165-00 07167-00

Packung mit 10 Stück
box of 10
en cajas de 10
confezione di 10

07109-10 10,0 cm, 4°
07109-13 13,0 cm, 5°
07109-15 15,5 cm, 6°

Skalpell-Klingen, Steril
 Scalpel Blades, Sterile
 Hojas de bisturí, estéril
 Lame per bisturi, sterili



07110-00



07111-00



07112-00



07113-00



07115-00



07115-00



07116-00



07118-00



07119-00



07120-00



07121-00



07122-00



07123-00



07124-00



07125-00



Produktionscharge
 Prod. Charge
 Numero di serie

Verfalldatum/Herstellungsdatum
 expire date/prod. date
 Data di scadenza

Indikator
 Indicator
 Indicatore

Packung mit 100 Stück
 in packages of 100 each
 en cajas de 100 c/u
 confezione di 100 pezzi

Skalpellklingen-Entferner
 Scalpel Blade Remover
 Quita hojas
 Distributore lame



07130-00

Einmal-Skalpelle, Steril
 Disposable Scalpels, Sterile
 Bisturíes uso único, estériles
 Bisturi monouso, sterili



07210-00

Packung mit 10 Stück
 in packages of 10 each
 en cajas de 10 c/u
 confezione di 10 pezzi



07211-00



07212-02



07213-00



07215-00



07215-01



07218-00



07219-00



07220-00



07221-00



07222-00



07223-00

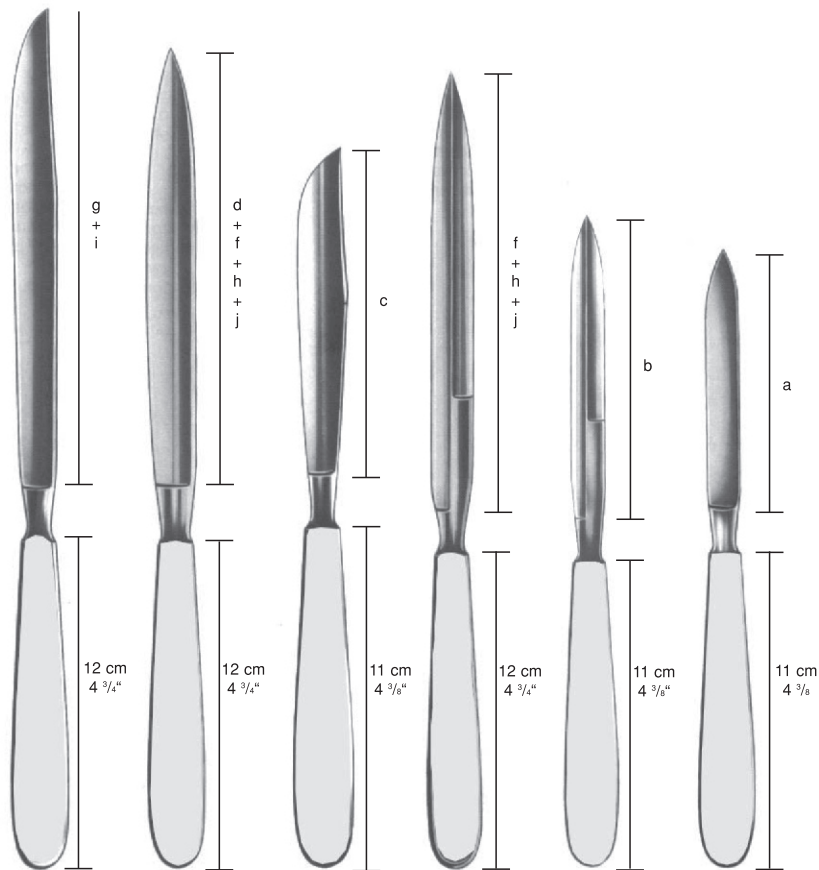


07224-00



07225-00

Amputationsmesser
Amputation Knives
Cuchillos para amputación
Coltelli per amputazione



Liston
07200-17
07200-20

Reda
07201-13
07201-16
07201-19
07201-22

Langenbeck
07202-12

Catlin
doppelschneidig
double
aftingedeges
filo doble
doppio taglio
07203-16
07203-19
07203-22

07204-11
Zwischenknochen-
messer doppel-
schneidig
Inerosseous knife
double aftingedeges
Cuchillo interóseo
filo doble
Coltello interosseo
doppio taglio

07205-09
Phalangen-
messer
Phalangeal knife
Cuchillos para
falanges
Coltello per falangi

Schnittlänge
Length of blades
Largo de hojas
Lunghezze delle lame

a - 9,5 cm	c - 12,0 cm	e - 15,0 cm	g - 17,0 cm	i - 20,0 cm
b - 11,0 cm	d - 13,0 cm	f - 16,0 cm	h - 19,0 cm	j - 22,0 cm
a - 3 3/4"	c - 4 3/4"	e - 6"	g - 6 3/4"	i - 8"
b - 4 3/8"	d - 5"	f - 6 1/4"	h - 7 1/2"	j - 8 3/4"

**Klingenbrecher, Rasierklingen
Blade Breakers, Razor Blades
Rompe-hojas, hojas de afeitar
Portilamette, Rompilamette**



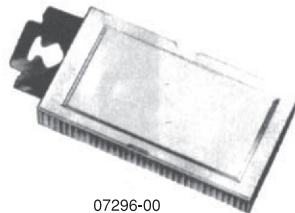
TROUTMAN-CHRIS
07290-09 9 cm, 3 1/2"



REDA
07291-11 11 cm, 4 3/8"



CASTROVIEJO
07294-13 13 cm, 5 1/8"



07296-00

Packung = 10 Stück
package = 10 each
Cajita = 10 c/u
Confezione = 10 pezzi

Skalpelle mit Metallheft
 Scalpels with Metal Handle
 Bisturíes, mango metálico
 Bisturi, manico di metallo



Fig. 1
 07402-01
 15 cm, 6"
 30 mm, 1.2"



Fig. 2
 07402-02
 15 cm, 6"
 36 mm, 1.4"



Fig. 3
 07402-03
 15.5 cm, 6"
 40 mm, 1 1/2"



Fig. 4
 07402-04
 16 cm, 6 1/4"
 45 mm, 1 3/4"



Fig. 5
 07402-05
 16 cm, 6 1/4"
 50 mm, 2"



Fig. 6
 07402-06
 15 cm, 6"
 27 mm, 1"



Fig. 7
 07402-07
 15 cm, 6"
 35 mm, 1.4"



Fig. 8
 07402-08
 16 cm, 6 1/4"
 40 mm, 1 1/2"

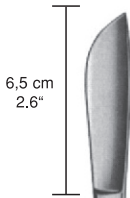


Fig. 9
 07402-09
 16 cm, 6 1/4"
 47 mm, 1.9"



Fig. 10
 07402-10
 17 cm, 6 3/4"
 50 mm, 2"

Resektions- und Knorpelmesser
 Resection and Cartilage Knives
 Cuchillos para resección/cartilagos
 Coltelli per resezione e cartilagini



6,5 cm
2.6"



6,5 cm
2.6"

Beinhautmesser
 mit Schaber
 Periosteum Knife
 with raspatory
 Cuchillo para
 periostio, con
 periostótamo
 Coltello per
 periostio con
 raschino

19 cm, 7 1/2"

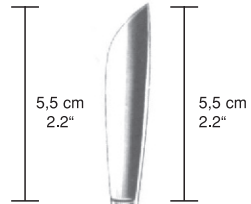
07403-01

Metallheft
 metal handle
 mango metálico
 manico di metallo

19 cm, 7 1/2"

07403-02

Holzheft
 wooden handle
 mango de madera
 manico in legno



5,5 cm
2.2"

5,5 cm
2.2"

07412-05

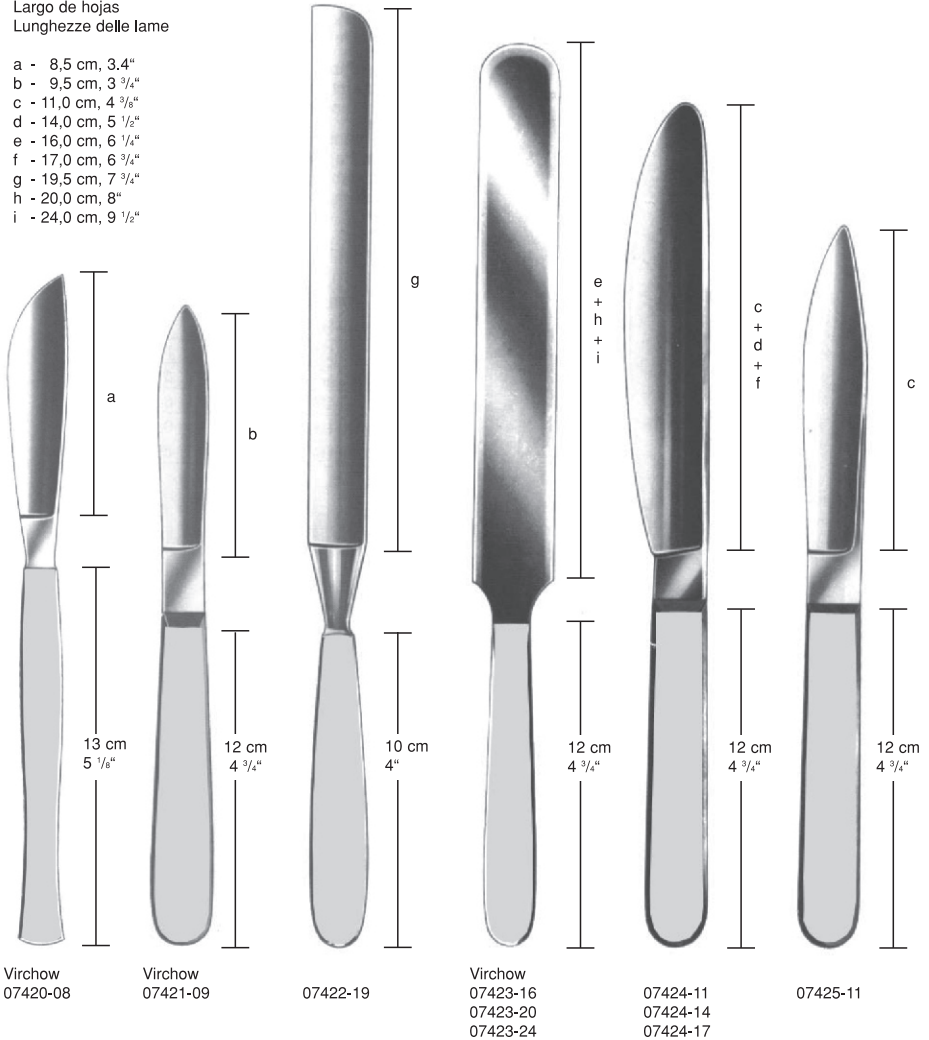
18 cm, 7"

07410-05
 Langenbeck

Sezier-, Hirn- und Organmesser
 Autopsy- Brain- and Post mortem knives
 Cuchillos para autopsia- cerebro- órganos
 Coltelli per cartilagini- cervello e organi

Schnittlänge
 Length of blades
 Largo de hojas
 Lunghezze delle lame

- a - 8,5 cm, 3.4"
- b - 9,5 cm, 3 3/4"
- c - 11,0 cm, 4 3/8"
- d - 14,0 cm, 5 1/2"
- e - 16,0 cm, 6 1/4"
- f - 17,0 cm, 6 3/4"
- g - 19,5 cm, 7 3/4"
- h - 20,0 cm, 8"
- i - 24,0 cm, 9 1/2"



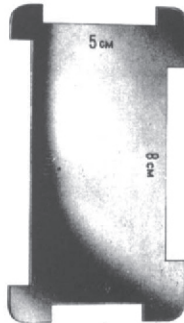
Dermatome, Rasiermesser
 Dermatome, Razor
 Dermátomo, Navajas
 Dermatomo, Rasoio



SCHINK
 07490-00
 30 cm, 11 3/4"
 0,1 - 2 mm
 compl.
 mit/with/con
 07490-01 (1) Stk./ pcs
 07490-02 (2) Stk./ pcs



07490-01
 Ersatzklinge
 Spare blade
 Hoja de repuesto
 Lama di ricambio per dermatomo

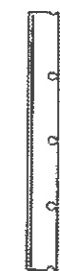
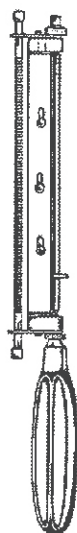


07490-02
 Spannplatte
 Skin straightening plate
 Placa para extender la piel
 Placca per stendipelle



07496-00
 Rasiermesser 8 cm, 3 1/8"
 Razors 8 cm, 3 1/8"
 Navajas 8 cm, 3 1/8"
 Rasoio 8 cm, 3 1/8"

Dermatome, Rasiermesser
 Dermatome, Razor
 Dermátomo, Navajas
 Dermatomo, Rasoio



07496-31

Ersatzklingen
 Spare blades pack
 Hoja de repuesto
 Lame di ricambio

HUBY
 07495-31 31 cm, 12 1/4"
 0,1 - 1,2 mm



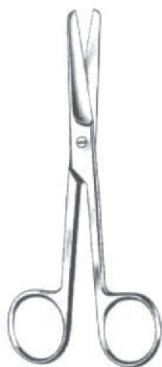
SILVER
 07498-00
 190 mm, 7 1/2"
 Dermatome, ohne Klingen
 Skin graft knife, without blade
 Senza lama utilizzo con lamette
 da barba normale



Klingen
 blades
 bisturi
 07499-01

WATSON
 07499-00
 300 mm, 11 3/4"
 Dermatome, ohne Klingen
 Skin graft knife, without blade
 Senza lama utilizzo con lamette
 da barba normale

Chirurgische Scheren
Operating Scissors
Tijeras para cirugía
Forbici per chirurgia



STANDARD

09102-11 11,5 cm, 4 1/2"
09102-13 13,0 cm, 5"
09102-14 14,5 cm, 5 3/4"
09104-14 TC
09102-15 15,5 cm, 6"
09102-16 16,5 cm, 6 1/2"
09102-18 18,5 cm, 7 1/4"
09102-20 20,0 cm, 8"



STANDARD

09110-11 11,5 cm, 4 1/2"
09110-13 13,0 cm, 5"
09110-14 14,5 cm, 5 3/4"
09114-14 TC
09110-15 15,5 cm, 6"
09110-16 16,5 cm, 6 1/2"
09110-18 18,5 cm, 7 1/4"
09110-20 20,0 cm, 8"



STANDARD

09120-11 11,5 cm, 4 1/2"
09120-13 13,0 cm, 5"
09120-14 14,5 cm, 5 3/4"
09124-14 TC
09120-15 15,5 cm, 6"
09120-16 16,5 cm, 6 1/2"
09120-18 18,5 cm, 7 1/4"
09120-20 20,0 cm, 8"



STANDARD

09103-11 11,5 cm, 4 1/2"
09103-13 13,0 cm, 5"
09103-14 14,5 cm, 5 3/4"
09105-14 TC
09103-15 15,5 cm, 6"
09103-16 16,5 cm, 6 1/2"
09103-18 18,5 cm, 7 1/4"
09103-20 20,0 cm, 8"



STANDARD

09111-11 11,5 cm, 4 1/2"
09111-13 13,0 cm, 5"
09111-14 14,5 cm, 5 3/4"
09115-14 TC
09111-15 15,5 cm, 6"
09111-16 16,5 cm, 6 1/2"
09111-18 18,5 cm, 7 1/4"
09111-20 20,0 cm, 8"



STANDARD

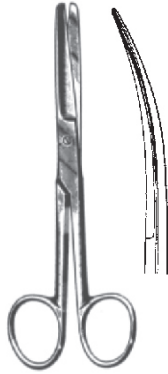
09121-11 11,5 cm, 4 1/2"
09121-13 13,0 cm, 5"
09121-14 14,5 cm, 5 3/4"
09125-14 TC
09121-15 15,5 cm, 6"
09121-16 16,5 cm, 6 1/2"
09121-18 18,5 cm, 7 1/4"
09121-20 20,0 cm, 8"

Präparierscheren
Dissecting Scissors
Tijeras de disección
Forbici per dissezione

Inzisionsschere – Incision Scissors – Tijera de incision – Forbici per incisione



09128-14
14,0 cm
5 1/2"



— DEAVER —
09130-14 14 cm 09131-14
5 1/2"



— DEAVER —
09140-14 14 cm 09141-14
5 1/2"



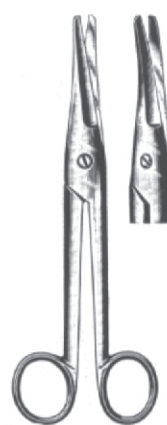
— DEAVER —
09150-14 14 cm 09151-14
5 1/2"



— MAYO —
09160-14 14,5 cm 09161-14
09164-14 TC 14,5 cm 09165-14 TC
09160-17 17,0 cm 09161-17
09164-17 TC 17,0 cm 09165-17 TC
09160-23 23,0 cm 09161-23
09164-23 TC 23,0 cm 09165-23 TC



— MAYO-STILLE —
09170-15 15,0 cm 09171-15
09174-15 TC 15,0 cm 09175-15 TC
09170-17 17,0 cm 09171-17
09174-17 TC 17,0 cm 09175-17 TC
09170-21 21,0 cm 09171-21
09174-21 TC 21,0 cm 09175-21 TC

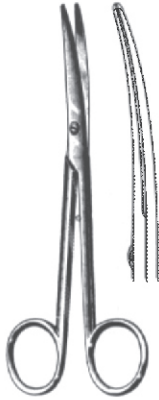


— MAYO-NOBLE —
09180-17 17,0 cm 09181-17
6 3/4"

Präparierscheren
Dissecting Scissors
Tijeras de disección
Forbici per dissezione



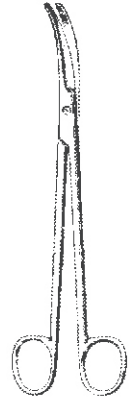
LEXER
09190-16
09194-16 TC
16 cm, 6 1/4"



LEXER
09191-16
09195-16 TC
16 cm, 6 1/4"



LEXER BABY
09202-10 09203-10
09206-10 TC 09207-10 TC
10 cm, 4"



JORGENSEN
09204-22
22 cm, 8 3/4"



METZENBAUM

09280-12 12 cm 09284-12 TC
09280-15 15 cm 09284-15 TC
09280-18 18 cm 09284-18 TC
09280-20 20 cm 09284-20 TC
09280-23 23 cm 09284-23 TC
09280-25 25 cm 09284-25 TC
09280-28 28 cm 09284-28 TC
09280-30 30 cm 09284-30 TC



METZENBAUM

09281-12 12 cm 09285-12 TC
09281-15 15 cm 09285-15 TC
09281-18 18 cm 09285-18 TC
09281-20 20 cm 09285-20 TC
09281-23 23 cm 09285-23 TC
09281-25 25 cm 09285-25 TC
09281-28 28 cm 09285-28 TC
09281-30 30 cm 09285-30 TC



METZENBAUM FINO

09282-15 15 cm 09286-15 TC
09282-18 18 cm 09286-18 TC
09282-20 20 cm 09286-20 TC
09282-23 23 cm 09286-23 TC
09282-25 25 cm 09286-25 TC
09282-28 28 cm 09286-28 TC



METZENBAUM FINO

09283-15 15 cm 09287-15 TC
09283-18 18 cm 09287-18 TC
09283-20 20 cm 09287-20 TC
09283-23 23 cm 09287-23 TC
09283-25 25 cm 09287-25 TC
09283-28 28 cm 09287-28 TC