

## GRIPPER® Huber Needles

### Technical Summary

#### DEVICE CLASSIFICATION

##### US Classification

Class II/§880.5540

##### Canada Classification

Class II, Rule 1

##### Australia Classification

Class IIa, Rule 3.2

#### DEVICE DESCRIPTION

This device is intended for single use only and is provided sterile and non-pyrogenic. The materials used to manufacture this device do not contain latex and are DEHP-free. This is an Rx Device.

#### GMDN

17180

#### CE MARK NUMBER

0086

#### INDICATIONS

This product is indicated for the administration into or withdrawal of fluids from implanted ports.

#### LEGAL MANUFACTURER

Smiths Medical ASD, Inc.  
6000 Nathan Lane North  
Minneapolis, MN 55442 USA

#### MANUFACTURING SITE NAME AND ADDRESS

Smiths Healthcare Manufacturing S.A.  
de C.V. Avenida Caliidad No. 4  
Parque Industrial Internacional Tijuana  
Tijuana, B.C.C.P. Baja CA 22425 Mexico

#### COUNTRY OF ORIGIN

Mexico

#### ANIMAL ORIGIN

None of the devices listed on this product family incorporate any substances that are derived from animal tissues as per Commission Regulation (EU) 722/2012.

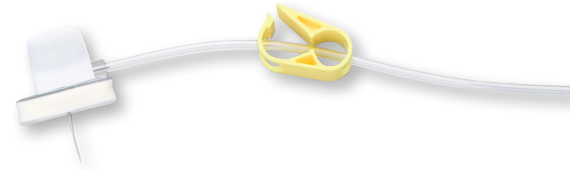
#### STERILIZATION METHOD

Ethylene Oxide

#### SHELF-LIFE

A 5-year expiration date is assigned to the product as long as the packaging is undamaged and unopened, based on accelerated aging stability shelf-life testing and real-time aging.

Not manufactured with DEHP plasticizer



#### COMPONENT COMPOSITIONS

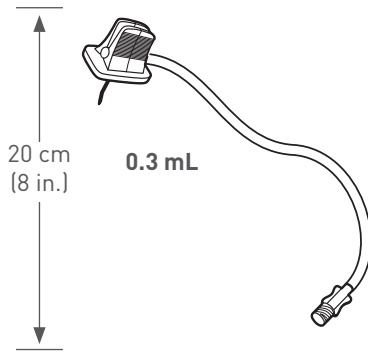
Clip	Acetal
Foam	EVA
Base & Pivot Arm	Acrylic Copolymer
Cannula	304 SS
Cannula Protector	LDPE
Tubing	PVC, TOTM
Clamp	Acetal
Female Luer	PVC, TOTM
Non-Vented Male Cap	Polypropylene

#### LABELLING AND PACKAGING

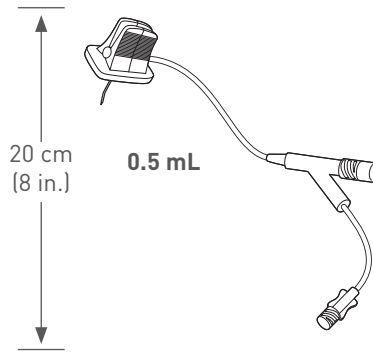
Container Type	Length	Width	Height	Weight
Unit Pack (1 unit)	101 mm	145 mm	2.2 mm	9.1 g
Shelf Pack	205 mm	92 mm	148 mm	245 g
Case Pack	492 mm	422 mm	406 mm	7.4 kg

MR conditional up to 3 Tesla

## PRIMING VOLUME



Without Y-Site Tubing



Y-Site Tubing

## PRODUCT RANGE AND SPECIFICATIONS

### GRIPPER® Huber Needles

Latex-free, non-coring, non-siliconized, removable contoured grip, cushioned needle platform, 8" extension tubing with or without Y-site

Y-site				
Removable injection cap on Luer-lock Y-site	Length	Reorder No.	UPC No.	Unit
22 gauge	5/8 inch	21-2938-24	(01) 3 0610586 02321 1	12/box
	3/4 inch	21-2939-24	(01) 3 0610586 01674 9	12/box
	1 inch	21-2940-24	(01) 3 0610586 01675 6	12/box
	1 ¼ inch	21-2941-24	(01) 3 0610586 01676 3	12/box
20 gauge	5/8 inch	21-2946-24	(01) 3 0610586 02323 5	12/box
	3/4 inch	21-2947-24	(01) 3 0610586 01677 0	12/box
	1 inch	21-2948-24	(01) 3 0610586 01678 7	12/box
	1 ¼ inch	21-2949-24	(01) 3 0610586 01679 4	12/box
19 gauge	3/4 inch	21-2955-24	(01) 3 0610586 01680 0	12/box
	1 inch	21-2956-24	(01) 3 0610586 01681 7	12/box
	1 ¼ inch	21-2957-24	(01) 3 0610586 01682 4	12/box
Without Y-site				
	Length	Reorder No.	UPC No.	Unit
22 gauge	5/8 inch	21-2737-24	(01) 3 0610586 02320 4	12/box
	3/4 inch	21-2733-24	(01) 3 0610586 01584 1	12/box
	1 inch	21-2714-24	(01) 3 0610586 01578 0	12/box
	1 ¼ inch	21-2715-24	(01) 3 0610586 01579 7	12/box
20 gauge	5/8 inch	21-2736-24	(01) 3 0610586 02322 8	12/box
	3/4 inch	21-2734-24	(01) 3 0610586 01585 8	12/box
	1 inch	21-2717-24	(01) 3 0610586 01580 3	12/box
	1 ¼ inch	21-2718-24	(01) 3 0610586 01581 0	12/box
19 gauge	3/4 inch	21-2735-24	(01) 3 0610586 01586 5	12/box
	1 inch	21-2720-24	(01) 3 0610586 01582 7	12/box
	1 ¼ inch	21-2721-24	(01) 3 0610586 01583 4	12/box

PRODUCT(S) DESCRIBED MAY NOT BE LICENSED OR AVAILABLE FOR SALE IN CANADA AND OTHER COUNTRIES

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