

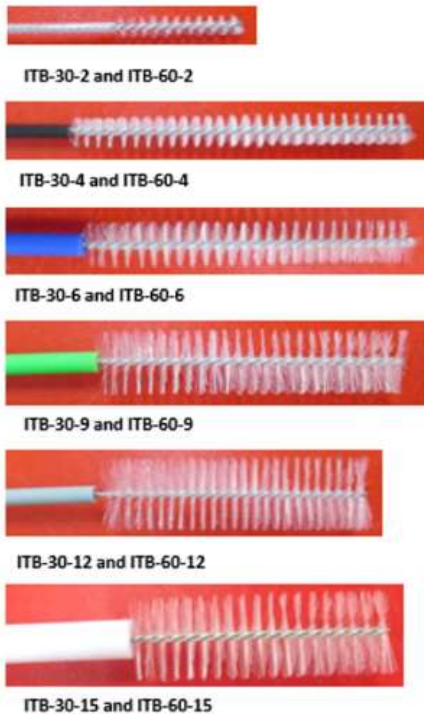


Force Testing of Instrument Tube Brushes

Product Codes: ITB-30-2, ITB-30-4, ITB-30-6, ITB-30-9, ITB-30-12, ITB-30-15, ITB-60-2, ITB-60-4, ITB-60-6, ITB-60-9, ITB-60-12, ITB-60-15

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Instrument Tube Brushes are used to clean the internal channels or lumens of lumened medical devices. Brushes play an important role in effective reprocessing after clinical use of the medical device. Healthmark's Instrument Tube Brushes range in diameter sizes of 2.0mm to 15.0mm, each available in lengths of 30.0cm and 60.0cm. It is important that the brush used for cleaning is intended for the desired channel size and intended use per the manufacturer. The brush diameter should be wider than it's intended channel diameter to allow for enough friction to occur between the brush part and lumen surface, so that removal of debris may occur. The cleaning effectiveness of a brush is related to the forces required to move a brush part in and out of a lumen, as outlined in ASTM F3725; *The Standard Guide for using a Force Tester to Evaluate the Performance of a Brush Part Designed to Clean the Internal Channel of a Medical Device*. In addition to the force required to move a brush within a tube, the removal of soil from a tube by the brush part moved in a tube is also a further indicator of cleaning effectiveness. The repetitive testing per brush allows for the assessment of effective cleaning forces and the level of soil removal.



Brush	Tube Length
ITB-30-2	30cm (11.8 in)
ITB-30-4	30cm (11.8 in)
ITB-30-6	30cm (11.8 in)
ITB-30-9	30cm (11.8 in)
ITB-30-12	30cm (11.8 in)
ITB-30-15	30cm (11.8 in)
ITB-60-2	60cm (23.6 in)
ITB-60-4	60cm (23.6 in)
ITB-60-6	60cm (23.6 in)
ITB-60-9	60cm (23.6 in)
ITB-60-12	60cm (23.6 in)
ITB-60-15	60cm (23.6 in)

The Instrument Tube Brushes (ITB) are named with the length of tubing (in cm) as the first number, and the brush diameter as the second number. All the ITB brushes are available in two lengths: 30cm and 60cm.

Following this standard, the friction between the brush and the interior lumen can be quantified in Compression (N) and Tension (N) with the use of a force tester apparatus and brush part being tested. The method to measure these forces was done at an established speed, under prescribed laboratory conditions as outlined in ASTM F3275. Each brush was tested in two different diameters of stainless steel, with five repeated runs for each diameter. Each run consisted of two consecutive cycles; repeated three times over, per run. First; compression, where the arm of the force tester, moves down into the lumen, a pre-determined distance. The second cycle is tension, where the arm of the force tester returns to the zero or starting position, traveling up and out of the lumen.

The soil removal capabilities of each brush was evaluated with two different diameters of PTFE tubing, three samples of each respective diameter size. All PTFE tubes were measured and cut to a pre-determined length, to ensure the brush being tested could insert and travel at least twice it's length without reaching the end of the tube. Each tube was weighed; before soiling, after soiling and drying overnight, and after cleaning each tube. These weights were then used to calculate the percent soil removal for each tube. The average of the three samples is then calculated and represents the average soil removal percentage for that specific brush and diameter tubing. One full run, with the same parameters per each of the three PTFE tubes was performed. Each run consisted of two consecutive cycles; repeated three times over, per run. First; compression, where the arm of the force tester, moves down into the lumen, a pre-determined distance. The second cycle is tension, where the arm of the force tester returns to the zero or starting position, traveling up and out of the lumen.

Each Instrument Tube Brush was tested in two different steel lumen diameters, and two different PTFE tubing diameters, respectively. One of the two diameters represents a smaller sized lumen the brush could be used on, while the other diameter chosen, represents a larger sized lumen the brush could be used on.

The ITB-30-2 and ITB-60-2 (MED-10318) was tested in a 1.5 mm, and 2.0 mm steel lumen and soiled PTFE tubing. The maximum compression for this brush part in 1.5 mm steel lumen was 1.63 N, and a maximum tension of 2.805 N. The maximum compression for the ITB-30-2 and ITB-60-2 in a 2.0 mm steel lumen was 0.48 N, with a maximum tension of 2.0 N. The cleaning efficiency in terms of average soil removal for this brush part in a 1.5 mm PTFE tubing was 99.30% and 98.70% in a 2.0 mm PTFE tubing (Tables 2 and 3).

The ITB-30-4 and ITB-60-4 (MED-10287) brush part was tested in a 2.0 mm, and 3.0 mm steel lumen and soiled PTFE tubing. The maximum compression for this brush part in 2.0 mm steel lumen was 4.170 N, and a maximum tension of 8.490 N. The maximum tension for the ITB-30-4 and ITB-60-4 in a 3.0 mm steel lumen was 4.05 N, with a maximum tension of 7.17 N. The cleaning efficiency in terms of average soil removal for this brush part in a 2.0 mm PTFE tubing was 98.31% and 97.62% in a 3.0 mm PTFE tubing (Tables 2 and 3).

The ITB-30-6 and ITB-60-6 (MED-10289) brush part was tested in a 3.0 mm, and 4.0 mm steel lumen and PTFE tubing. The maximum compression for this brush part in a 3.0 mm steel lumen was 4.385 N, and a maximum tension of 5.13 N. The maximum compression for the ITB-30-6 and ITB-60-6 in a 4.0 mm steel lumen was 3.15 N, with a maximum tension of 4.74 N. The cleaning efficiency in terms of average soil removal for this brush part in 3.0 mm PTFE tubing was 91.93%, and 87.90% in a 4.0 mm PTFE tubing (Tables 2 and 3).

The ITB-30-9 and ITB-60-9 (MED-10300) brush part was tested in a 5.0 mm, and 7.0 mm steel lumen and soiled PTFE tubing. The maximum compression for this brush part in a 5.0 mm steel lumen was 3.195 N, and a maximum tension of 3.44 N. The maximum compression for the ITB-30-9 and ITB-60-9 in a 7.0 mm steel lumen was 2.79 N, with a maximum tension of 3.755 N. The cleaning efficiency in terms of average soil removal for this brush part in 5.0 mm PTFE tubing was 99.67%, and 98.30% in a 7.0 mm PTFE tubing (Tables 2 and 3).

The ITB-30-12 and ITB-60-12 (MED-10475) was tested in a 7.0 mm, and 9.0 mm steel lumen and soiled PTFE tubing. The maximum compression for this brush part in a 7.0 mm steel lumen was 2.135 N, and a maximum tension of 3.950 N. The maximum compression for the ITB-30-12 and ITB-60-12 in a 9.0 mm steel lumen was 1.205 N, with a maximum tension of 1.795 N. The cleaning efficiency in terms of average soil removal for this brush part in 7.0 mm PTFE tubing was 100%, and 100% in a 9.0 mm PTFE tubing (Tables 2 and 3).

The ITB-30-15 and ITB-60-15 (MED-10523) was tested in a 9.0 mm, and 11.0 mm steel lumen and soiled PTFE tubing. The maximum compression for this brush part in a 9.0 mm steel lumen was 2.455 N, and a maximum tension of 1.380 N. The maximum compression for the ITB-30-15 and ITB-60-15 in an 11.0 mm steel lumen was 1.355 N, with a maximum tension of 1.80 N. The cleaning efficiency in terms of average soil removal for this brush part in a 9.0 mm PTFE tubing was 97.60%, and 100% in an 11.0 mm PTFE tubing (Tables 2 and 3).

Brush Part Code	ITB Brush Number	Diameter of Brush Filament	Diameter of brush part	Length of brush part	Filament type	Brush Tubing Length
MED-10318	ITB-30-2	0.0762 mm	2.0 mm	12.7 mm	Tynex Natural	30.0 cm
MED-10318	ITB-60-2	0.0762 mm	2.0 mm	12.7 mm	Tynex Natural	60.0 cm
MED-10287	ITB-30-4	0.1016 mm	4.0 mm	43.0 mm	Tynex Natural	30.0 cm
MED-10287	ITB-60-4	0.1016 mm	4.0 mm	43.0 mm	Tynex Natural	60.0 cm
MED-10289	ITB-30-6	0.1524 mm	6.0 mm	44.5 mm	Tynex Natural	30.0 cm
MED-10289	ITB-60-6	0.1524 mm	6.0 mm	44.5 mm	Tynex Natural	60.0 cm
MED-10300	ITB-30-9	0.1524 mm	9.0 mm	44.5 mm	Tynex Natural	30.0 cm
MED-10300	ITB-60-9	0.1524 mm	9.0 mm	44.5 mm	Tynex Natural	60.0 cm
MED-10475	ITB-30-12	0.1524 mm	12.0 mm	48.5 mm	Tynex Natural	30.0 cm
MED-10475	ITB-60-12	0.1524 mm	12.0 mm	48.5 mm	Tynex Natural	60.0 cm
MED-10523	ITB-30-15	0.1524 mm	15.0 mm	43.5 mm	Tynex Natural	30.0 cm
MED-10523	ITB-60-15	0.1524 mm	15.0 mm	43.5 mm	Tynex Natural	30.0 cm

Table 1. ITB Brush Specifics

Brush Part Code	ITB Number	Steel Lumen Diameter	Maximum Compression (N)	Maximum Tension (N)	Average Compression (N)	Average Tension (N)
MED-10318	ITB-30-2	1.5 mm	1.63 N	2.805 N	0.905 N	1.245 N
MED-10318	ITB-30-2	2.0 mm	0.48 N	2.0 N	0.145 N	0.585 N
MED-10318	ITB-60-2	1.5 mm	1.63 N	2.805 N	0.905 N	1.245 N
MED-10318	ITB-60-2	2.0 mm	0.48 N	2.0 N	0.145 N	0.585 N
MED-10287	ITB-30-4	2.0 mm	4.170 N	8.490 N	2.820 N	3.345 N
MED-10287	ITB-30-4	3.0 mm	4.05 N	7.17 N	2.79 N	3.315 N
MED-10287	ITB-60-4	2.0 mm	4.170 N	8.490 N	2.820 N	3.345 N
MED-10287	ITB-60-4	3.0 mm	4.05 N	7.17 N	2.79 N	3.315 N
MED-10289	ITB-30-6	3.0 mm	4.385 N	5.13 N	2.405 N	2.78 N
MED-10289	ITB-30-6	4.0 mm	3.15 N	4.74 N	1.77 N	3.015 N
MED-10289	ITB-60-6	3.0 mm	4.385 N	5.13 N	2.405 N	2.78 N
MED-10289	ITB-60-6	4.0 mm	3.15 N	4.74 N	1.77 N	3.015 N
MED-10300	ITB-30-9	5.0 mm	3.195 N	3.44 N	1.755 N	2.4 N
MED-10300	ITB-30-9	7.0 mm	2.79 N	3.755 N	1.845 N	1.79 N
MED-10300	ITB-60-9	5.0 mm	3.195 N	3.44 N	1.755 N	2.4 N
MED-10300	ITB-60-9	7.0 mm	2.79 N	3.755 N	1.845 N	1.79 N
MED-10475	ITB-30-12	7.0 mm	2.135 N	3.950 N	1.510 N	1.955 N
MED-10475	ITB-30-12	9.0 mm	1.205 N	1.795 N	0.750 N	0.905 N
MED-10475	ITB-60-12	7.0 mm	2.135 N	3.950 N	1.510 N	1.955 N
MED-10475	ITB-60-12	9.0 mm	1.205 N	1.795 N	0.750 N	0.905 N
MED-10523	ITB-30-15	9.0 mm	2.455 N	1.380 N	0.915 N	0.950 N
MED-10523	ITB-60-15	11.0 mm	1.355 N	1.80 N	0.760 N	0.835 N
MED-10523	ITB-30-15	9.0 mm	2.455 N	1.380 N	0.915 N	0.905 N
MED-10523	ITB-60-15	11.0 mm	1.355 N	1.80 N	0.760 N	0.835 N

Table 2. Forces required to move the ITBs in and out of their respective steel lumens

Brush Part Code	ITB Brush Number	PTFE Tubing Diameter	Soil Removal %
MED-10318	ITB-30-2	1.5 mm	99.30%
MED-10318	ITB-30-2	2.0 mm	98.70%
MED-10318	ITB-60-2	1.5 mm	99.30%
MED-10318	ITB-60-2	2.0 mm	98.70%
MED-10287	ITB-30-4	2.0 mm	98.31%
MED-10287	ITB-30-4	3.0 mm	97.62%
MED-10287	ITB-60-4	2.0 mm	98.31%
MED-10287	ITB-60-4	3.0 mm	97.62%
MED-10289	ITB-30-6	3.0 mm	91.93%
MED-10289	ITB-30-6	4.0 mm	87.90%
MED-10289	ITB-60-6	3.0 mm	91.93%
MED-10289	ITB-60-6	4.0 mm	87.90%
MED-10300	ITB-30-9	5.0 mm	99.67%
MED-10300	ITB-30-9	7.0 mm	98.30%
MED-10300	ITB-60-9	5.0 mm	99.67%
MED-10300	ITB-60-9	7.0 mm	98.30%
MED-10475	ITB-30-12	7.0 mm	100%
MED-10475	ITB-30-12	9.0 mm	100%
MED-10475	ITB-60-12	7.0 mm	100%
MED-10475	ITB-60-12	9.0 mm	100%
MED-10523	ITB-30-15	9.0 mm	97.60%
MED-10523	ITB-60-15	11.0 mm	100%
MED-10523	ITB-30-15	9.0 mm	97.60%
MED-10523	ITB-60-15	11.0 mm	100%

Table 3. Average soil removal (%) for ITBs, respective to the PTFE diameter tubing used.

By using an objective, quantifiable and reproducible procedure as outlined in ASTM F3275, we were able to evaluate the cleaning efficacy of each ITB Brush. All the brushes removed at least 87.90%, and most removed 97.62% of the soil, or more (Table 3).