

## 〈871〉 SUTURES—NEEDLE ATTACHMENT

### Change to read:

Absorbable <sup>▲</sup> (USP 1-Dec-2019) and nonabsorbable surgical sutures with standard needle attachment are such that the needles are firmly attached and are not intended to be separated. Sutures supplied with eyeless needles attached fall into either the category of standard needle attachment or the category of removable needle attachment. Removable needle attachment of both absorbable and nonabsorbable surgical sutures is such that the needle may be deliberately separated from the suture by means of a quick tug. Both types of attachments are tested on equipment as specified in *Tensile Strength* 〈881〉.

### Change to read:

## PROCEDURE

Clamp each of 5 sutures in the <sup>▲</sup>tensile testing device <sup>▲</sup> (USP 1-Dec-2019) so that the needle is in the fixed clamp with all of the swaged portion exposed and in line with the direction of force applied to the suture by the moving clamp. Determine the force required to detach the suture from the needle. In the case of standard needle attachment, the suture may break without needle detachment.

### Standard Needle Attachment

The requirements are met if neither the average of the 5 values nor any individual value is less than the <sup>▲</sup>limits <sup>▲</sup> (USP 1-Dec-2019) given for the designated size in *Table 1*.

**Table 1. Standard Needle Attachment for Absorbable and Nonabsorbable Sutures**

Metric Size (gauge no.)		Limits on Needle Attachment				
Absorbable Collagen Suture	Nonabsorbable and Synthetic Absorbable Sutures	USP Size	Average (in kgf) (min.)	Individual (in kgf) (min.)	Average (in N) (min.)	Individual (in N) (min.)
—	0.1	11-0 <sup>▲</sup> and smaller <sup>▲</sup> (USP 1-Dec-2019)	0.007	0.005	0.069	0.049
—	0.2	10-0	0.014	0.010	0.137	0.098
0.4	0.3	9-0	0.021	0.015	0.206	0.147
0.5	0.4	8-0	0.050	0.025	0.490	0.245
0.7	0.5	7-0	0.080	0.040	<sup>▲</sup> 0.785 <sup>▲</sup> (USP 1-Dec-2019)	0.392
1	0.7	6-0	0.17	0.08	1.67	0.784
1.5	1	5-0	0.23	0.11	<sup>▲</sup> 2.26 <sup>▲</sup> (USP 1-Dec-2019)	1.08
2	1.5	4-0	0.45	0.23	4.41	<sup>▲</sup> 2.26 <sup>▲</sup> (USP 1-Dec-2019)
3	2	3-0	0.68	0.34	6.67	3.33
3.5	3	2-0	1.10	0.45	10.8	4.41
4	3.5	0	1.50	0.45	14.7	4.41
5	4	1	1.80	0.60	<sup>▲</sup> 17.7 <sup>▲</sup> (USP 1-Dec-2019)	5.88
6 and larger	5 and larger	2 and larger	1.80	0.70	<sup>▲</sup> 17.7 <sup>▲</sup> (USP 1-Dec-2019)	6.86

### Removable Needle Attachment

<sup>▲</sup>For USP sizes 5-0 through 2-0, <sup>▲</sup> (USP 1-Dec-2019) the requirements are met if the individual values of the 5 sutures are <sup>▲</sup>NLT 0.028 kgf (0.275 N) and NMT 1.59 kgf (15.6 N). <sup>▲</sup> (USP 1-Dec-2019)

[NOTE—For either type of attachment, if NMT one of the individual values falls outside the prescribed limits, repeat the test on an additional 10 sutures. The requirements of the test are met if none of the 10 additional values falls outside the individual limit requirements.]

<sup>▲</sup> <sup>▲</sup> (USP 1-Dec-2019)