

SITZMARKS®

RADIOPAQUE MARKERS

INDICATION: Adult patients with severe constipation but otherwise negative GI evaluations. SITZMARKS are to be dispensed only by physicians to patients for oral intake.

SUGGESTED DIRECTIONS TO THE PHYSICIAN:

SIMPLIFIED SITZMARKS METHOD

STEP 1:

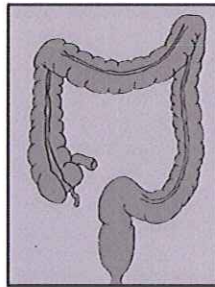
(1 capsule: each capsule with 24 markers)

1. On day 1, direct patient to take one SITZMARKS capsule by mouth with water, preferably with confirmation by office observation. Instruct patient to use no laxatives, enemas or suppositories for 5 days.
2. Arrange a flat plate abdominal X-ray on day 5 to determine the location and extent of elimination of the radiopaque markers.
3. Patients who expel at least 80% (19 or more) of the markers have grossly normal colonic transit.
4. Patients who retain 6 or more markers may have follow-up abdominal X-rays within several days.
5. For patients whose markers accumulate in the rectosigmoid or when markers are retained diffusely, **STEP 2** may be warranted.

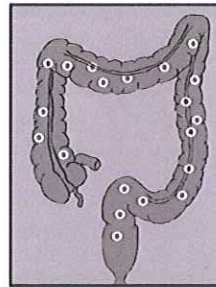
STEP 2: If more than 20% (5-6 markers) are still retained by day 5

1. Have patient take a bulking agent (such as KONSYL®) daily for 1 to 2 weeks. Encourage liquid intake to maximize product efficacy.
2. Have patient take another SITZMARKS capsule in 1 to 2 weeks and repeat X-rays in 5 days to determine the location and extent of elimination of the markers.

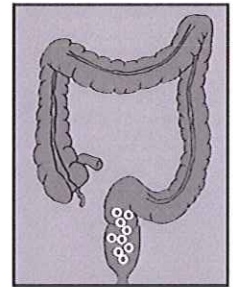
READING THE RESULTS: If over 80% of the markers are passed by day 5, colonic transit is not grossly abnormal. If the remaining markers are scattered about the colon, the condition is most likely hypomotility or colonic inertia. If the remaining markers are accumulated in the rectum or rectosigmoid, the condition is most likely functional outlet delay, e.g., internal rectal prolapse, anismus.



A. If 5 or less markers remain, patient has grossly normal colonic transit.



B. Most rings are scattered about the colon. Patient most likely has hypomotility or colonic inertia.



C. Most rings are gathered in the rectosigmoid. Patient has functional outlet obstruction.

SEGMENTAL SITZMARKS METHOD

(3 capsules: each capsule with 24 markers or

3 capsules: each capsule with 24 markers-available in 3 different shapes)

Take the O marker on day 1; the Double D marker on day 2, and the Tri-Chamber marker on day 3.

METCALF PROTOCOL:

1. On day 1, day 2, and day 3, administer one Sitzmarks capsule by mouth with water, preferably with confirmation by office observation. Instruct patient to use no laxatives, enemas or suppositories for the duration of the test.
2. Arrange a flat plate abdominal X-ray on day 4 and, if necessary, again on day 7 to determine the location and extent of elimination of the radiopaque markers.
3. The total number of markers in each segment is used to determine transit time regardless of the type.

EXAMPLE: Total number of markers present in each segment will be equivalent to the transit time in hours

	Right Colon	Left Colon	Rectosigmoid	Colon
4th day	12	14	14	40
7th day	0	0	2	2
Transit Time	12 hours	14 hours	16 hours	42 hours

Normal Values:

Right Colon	= 11.3 hours
Left Colon	= 11.3 hours
Rectosigmoid	= 12.4 hours
Total	35 hours

4. On day 4, if there are more than 50 markers, transit time is abnormal and an x-ray needs to be taken at day 7.
5. If total colonic transit time is > 70 hours, then transit in any segment is abnormal if > 30 hours. (> = more than)



10 capsules per package. Each gelatin capsule contains 24 radiopaque polyvinyl chloride markers of 1mm x 4.50mm. Each marker is impregnated with barium sulfate.

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